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By _____
(Signature of person mailing)

John C. Martin
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: John WALKER	:	
APPLICATION NO.: 09/857,797	:	Examiner: Yunsoo Kim
FILING DATE: June 11, 2001	:	Group Art Unit: 1644
TITLE: IMPROVED SAPONIN ADJUVANT COMPOSITIONS AND METHOD RELATING THERETO	:	

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

Sir:

Petition to Revive Unintentionally Abandoned Application – 37 CFR 1.137(b)/1.17(m)

Applicant herein respectfully petitions for revival of the above-identified application, which was unintentionally abandoned for failure to properly respond to a Non-Final Official Action mailed November 22, 2005. The Reply to the Non-Final Office Action, which is attached hereto as Exhibit A, was timely filed and received by the Patent Office on May 22, 2006. A Notice of Non-Compliant Amendment was mailed by the Patent Office on June 2, 2006, but was never received by any attorney within Pfizer. Thereafter, a Notice of Abandonment was mailed on January 24, 2007.

The present application is part of a portfolio of cases for which prosecutorial responsibility was transferred into the Patent Department of Pfizer, Inc., from an outside law firm which was then representing its client, CSL Limited, of Australia. Relevant parts of CSL Limited's patent portfolio, including the present application, have been acquired by Pfizer Inc.

Pursuant to 37 CFR 1.137(b)(3), the undersigned attorney hereby certifies that the entire period of delay (including up until the mailing of the present Petition) in regard to the above-identified application was unintentional. Relevant events leading to the unintentional abandonment, and continuing up to the present date, are as follows.

It is submitted that the Reply to the November 22, 2005 Office Action constituted a good-faith attempt to properly and timely reply to the Non-Final Office Action. The Reply provided a complete and comprehensive response to all issues raised by the Examiner in the November 22, 2005 Office Action, but was deemed non-compliant solely because of a single defect in the presentation of the Claim Listing. More specifically, as a matter of mere administrative error, the Claim Listing failed to indicate that Claims 1-22 of the application had previously been canceled – a defect that has only recently come to our attention. A substitute Reply, containing a proper Claim Listing, is submitted herewith, and attached hereto as Exhibit B.

As stated above, on June 2, 2006, the Office mailed a Notice of Non-Compliant Amendment to the outside law firm, which had previous responsibility for the present application as a result of its representation of CSL Ltd. Records kept by the law firm indicate that it forwarded the Notice to the undersigned at Pfizer, but the Notice was never received, as evidenced by it not being docketed or recorded in any of our database systems. As a result, no attorney within Pfizer responsible for the matter was aware that such Notice had ever issued.

Thereafter, the Patent Office mailed a Notice of Abandonment to the outside law firm, alleging failure to respond to the Notice of Non-Compliant Amendment. While the firm sent a letter to Pfizer in May 2007 forwarding the Notice of Abandonment, the letter, which is attached hereto as Exhibit C, was, for reasons unknown, sent to a Pfizer facility in La Jolla, California, rather than to Pfizer's corporate headquarters in New York, which the firm knew was the responsible legal department of Pfizer. As a result, the letter forwarding the Notice of Abandonment was not properly filed as an "Office Action" (or as an item for which any reply was due, or for which some action needed to be taken). Nor was any attorney or legal department staff member in New York contacted by any persons in Pfizer, La Jolla reporting the existence of the Notice of Abandonment. As a result, the Notice was never entered on any docket report, and no attorney within Pfizer was aware that the application had gone abandoned. No attorney at the outside law firm ever contacted a Pfizer attorney to report the abandonment.

The Notice of Abandonment was only recently discovered after investigation was made in an attempt to determine why an Office Action had not issued in response to the May 2006 Reply. Indeed, previous diligent internal inquiries (see emails attached hereto as Exhibit D), showing the efforts of E. Victor Donahue, Senior Patent Counsel of Pfizer Inc., to audit all available internal files) failed to uncover the Notice of Abandonment.

Therefore it is submitted that the entire period of delay in responding herein has been unintentional.

Pursuant to 37CFR 1.137(d), no Terminal Disclaimer is needed since the present application was filed after June 8, 1995. The Petition Fee of $1,500.00, 37 CFR 1.17(m), or any other needed fee or fee amount, should be charged to Applicant's Deposit Account, No. 16-1445, and any additional fees that the Patent Office determines are needed in connection with this Petition (such as for a Petition for Extension of Time, if any) may also be charged to this Deposit Account.

An early and favorable action is respectfully requested.

Respectfully submitted,

Date: December 21, 2007

John C. Martin
Reg. No. 42,843

Pfizer Inc.
Patent Department, 5th Floor
150 East 42nd Street
New York, NY 10017-5755
(212) 733-0538

EXHIBIT A

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of May, 2006.

By V A Yarisantos
(Signature of person mailing)

Violeta A. Yarisantos
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: John WALKER

APPLICATION NO.: 09/857,797 — Examiner: Yunsoo Kim

FILING DATE: June 11, 2001 — Group Art Unit: 1644

TITLE: IMPROVED SAPONIN ADJUVANT COMPOSITIONS AND METHOD RELATING THERETO

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. §1.111

In response to the Office Action mailed November 22, 2005, please consider the following remarks intended to place the subject application into form for allowance. Applicant submits concurrently herewith a Petition for Extension of Time under 37 C.F.R. §1.136(a) (in duplicate) for a period of three (3) months from February 22, 2006 up to and including May 22, 2006, accompanied by a provision authorizing payment of the appropriate fee. Accordingly, this response is timely filed.

The listing of claims begins on page 2 of this document.

Remarks begin on page 4 of this document.

Listing of Claims:

23. (Previously Presented) An adjuvant composition, comprising (A) an ionic polysaccharide and (B) an immunostimulating complex that comprises (i) a saponin and (ii) cholesterol, wherein the mass ratio of the ionic polysaccharide to the immunostimulating complex is in the range of 50 to 300.

24. (Previously Presented) The adjuvant composition of claim 23, wherein the ionic polysaccharide is an ionic dextran.

25. (Previously Presented) The adjuvant composition of claim 24, wherein the ionic dextran is DEAE-dextran.

26. (Previously Presented) The adjuvant composition of claim 23, wherein the immunostimulating complex is a protein-free immunostimulating complex.

27. (Previously Presented) The adjuvant composition of claim 23, wherein the immunostimulating complex further comprises a phospholipid, and wherein the saponin is Quil A.

28. (Previously Presented) The adjuvant composition of claim 23, wherein the mass ratio of ionic polysaccharide component to immunostimulating complex component is in the range of about 100 to about 140.

29. (Previously Presented) The adjuvant composition of claim 28, wherein the mass ratio is about 125.

30. (Previously Presented) The adjuvant composition of claim 23, comprising about 10 mg of the ionic polysaccharide and about 80 μg of the immunostimulating complex, wherein the ionic polysaccharide is DEAE-dextran.

31. (Previously Presented) The adjuvant composition of claim 23, comprising about 100 mg of the ionic polysaccharide and about 800 μg of the immunostimulating complex, wherein the ionic polysaccharide is DEAE-dextran.

32. (Previously Presented) An immunogenic composition comprising an immunogen and the adjuvant composition of claim 23.

33. (Previously Presented) The immunogenic composition of claim 32, wherein said immunogen comprises LHRH.

34. (Previously Presented) The immunogenic composition of claim 33, wherein said immunogen comprises an LHRH-diphtheria toxoid conjugate.

35. (Previously Presented) The immunogenic composition of claim 34, comprising from about 5 to about 500 μg of LHRH-diphtheria toxoid conjugate, from about 5 to about 500 mg of the ionic polysaccharide, and from about 40 to about 4000 μg of the immunostimulating complex.

36. (Previously Presented) A pharmaceutical composition, comprising (i) the immunogenic composition of claim 32, and (ii) one or more pharmaceutically acceptable carriers.

37. (Previously Presented) A method of eliciting an effective immune response in an animal, comprising administering to an animal an effective amount of the immunogenic composition of claim 32.

38. (Previously Presented) The method of claim 37, wherein said composition further comprises one or more pharmaceutically acceptable carriers.

Remarks

Claims 23-38 are pending in the present application. The claims have been rejected under 35 U.S.C. §103 for alleged obviousness. In particular, the rejection alleges that the claims are unpatentable over United States Patent No. 5,403,586 (hereinafter, "the '586 patent) as is evidenced by WO 96/11711 ("the '711 publication") in view of United States Patent No. 6,528,058 ("the '058 patent") and WO 99/02180 ("the '180 publication"). The rejection has been carefully considered, but is most respectfully traversed.

The presently claimed invention is, *inter alia*, directed to adjuvant compositions that comprise an ionic polysaccharide and an immunostimulating complex (or "iscom"), wherein the mass ratio of the ionic polysaccharide to the iscom is in the range of 50 to 300.

In the rejection, it is urged that: (1) the '586 patent teaches vaccine compositions comprising LHRH and a saponin adjuvant combined with DEAE-dextran; (2) the '058 patent teaches the claimed molar ratio of saponin component to polycationic polyeletrolyte (e.g., DEAE-dextran); and (3) the '180 publication teaches immunogenic LHRH-diptheria toxiod ("DT") conjugates for use in fertility and/or reproduction control. Thus, the rejection alleges that "one of ordinary skill in the art would have been motivated to combine the molar ratio . . . taught by the '058 patent to the LHRH-DT taught by the '180 publication to the LHRH vaccine composition comprising saponin and DEAE-dextran taught by the '586 patent . . . ." (Office Action, dated November 22, 2005, at page 3). For the reasons that follow, this rejection is respectfully traversed.

Applicant respectfully wishes to direct the Examiner's attention to the basic criteria for establishing a prima facie case of obviousness as set forth in the MPEP §2143. First, there must be some suggestion or motivation to combine the teachings of the individual references cited. Second, there must be a reasonable expectation that such combination would be successful. Finally, the prior art references, when combined, must teach or suggest each of the claimed limitations. It is respectfully submitted that at least two of the above three requirements have not been met here.

In particular, in the present situation, the rejection is based in large part on the teachings of the '180 publication. However, Applicant respectfully submits that any reliance on such publication is improper because the '180 publication does not qualify

as prior art. The '180 publication published January 21, 1999, which is after the filing date of the application from which the present application claims priority. Thus, the '180 publication is not available as prior art; and Applicant respectfully requests that the rejection be withdrawn.

In so far as the '586 and '058 patents are concerned, one of ordinary skill in the art would find no motivation to combine their respective teachings. In particular, the '586 patent relates to the preparation of LHRH fusion proteins – not LHRH conjugates. Indeed, the '586 patent specifically **teaches away** from the preparation of conjugates: "Chemical conjugation is, however, difficult to control and often results in a heterogeneous and ill-defined product." ('586 patent at col. 2, lines 18-19). In contrast to conjugation, the '586 patent teaches the fusion of LHRH analogue coding sequences to particular insertion sites in TraTp coding sequences.

The '058 patent is directed to adjuvant compositions for stimulating an immune response to an antigenic substance. The '058 patent, however, makes no reference to fusion proteins; instead, it describes the antigenic substances as chemical conjugates. Accordingly, because the '586 patent teaches away from the use of such conjugates, one of ordinary skill in the art would find no motivation to combine its teachings with those of the '058 patent. Thus, Applicant respectfully requests that the rejection be withdrawn.

In addition, even, assuming for the sake of argument only, that some motivation could be found to combine the teachings of the '586 and '058 patents, the resulting combination would not teach or suggest each and every limitation of the presently clamed invention. In this regard, the '058 patent makes no reference to LHRH; and neither patent makes any reference to LHRH conjugates in general, DT, or conjugates of DT and LHRH. Likewise, the '711 publication, which is relied upon in the rejection to establish that saponins in the form of iscoms can be used as adjuvants, contains no disclosure or suggestion concerning LHRH, DT, or conjugates of LHRH and DT. Consequently, any combination of the references cited would – at best – result in vaccines comprising LHRH-TraTp fusion proteins and saponin (or iscom) adjuvants of the '058 patent (or '711 publication). Thus, because such combination would not teach or suggest the claimed LHRH-DT conjugates, Applicant respectfully requests that the rejection be withdrawn.

Applicant respectfully requests that the foregoing remarks be entered and made of record in the present application. In addition, applicant respectfully requests consideration of the pending claims and early allowance of the application. No additional fee is believed due. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

Respectfully submitted,

Date: May 22, 2006

John C. Martin
Reg. No. 42,843

Pfizer Inc.
Patent Department, 5th Floor
150 East 42nd Street
New York, NY 10017-5755
(212) 733-6872

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of May, 2006.

By V Qyarisantos
(Signature of person mailing)

Violeta A. Yarisantos
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: John WALKER	:	
APPLICATION NO.: 09/857,797	:	Examiner: Yunsoo Kim
FILING DATE: June 11, 2001	:	Group Art Unit: 1644
TITLE: IMPROVED SAPONIN ADJUVANT COMPOSITIONS AND METHOD RELATING THERETO	:	

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

Sir:

PETITION FOR EXTENSION OF TIME

Pursuant to the provisions of 37 C.F.R. §1.136(a), it is respectfully requested that the time for response to the Office Action, dated November 22, 2005, and having an original period for response of three (3) months, be extended by three (3) months from February 22, 2006 up to and including May 22, 2006.

Authorization is hereby provided to charge the amount of $1020.00, as stated under 37 C.F.R. §1.17, as well as any additional fees required, or to credit any overpayment to Deposit Account No. 16-1445. Two copies of this paper are enclosed.

Respectfully submitted,

Date: May 22, 2006

John C. Martin
Reg. No. 42,843

Pfizer Inc.
Patent Department, 5th Floor
150 East 42nd Street
New York, NY 10017-5755
(212) 733-6872

Date Mailed: May 22, 2006 Express Mail No. _____

Serial No. 09/857,797 Docket No. PC22142 By JCM

Application of John Walker Filing Date June 11, 2001

Entitled IMPROVED SAPONIN ADJUVANT COMPOSITIONS AND METHOD RELATING THERETO

RECORDABLE

The following, has been received in the United States Patent and Trademark Office on the date stamped hereon:

- ☐ Application Transmittal *Type:*
- ☐ Specification *pages*
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- ☐ Drawing(s) *sheets*
- ☐ Declaration with Power of Attorney
- ☐ Priority Document
- ☐ Disclosure Statement
- ☐ Form PTO-FB-A820 (Citation List) References
- ☐ Sequence Submission (☐ Computer Readable Copy, ☐ Paper copy ☐ Identity Statement)
- ☐ Copy of Notice to File Missing Parts, Cover Letter
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- ☐ Associate Power of Attorney
- ☐ Petition for Expedited Issuance for Foreign Filing License
- ☐ Assignment & Recordation Cover Sheet
- ☒ Response to Office Action Under 37 C.F.R. §1.111
- ☐
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Date Mailed: May 22, 2006 Express Mail No. _____

Serial No. 09/857,797 Docket No. PC22142 By JCM

Application of John Walker Filing Date June 11, 2001

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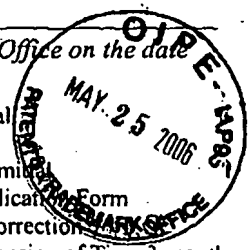

- ☐ Application Transmittal *Type:*
- ☒ Specification *pages*
- ☐ Claims *pages*
- ☐ Abstract *pages*
- ☐ Drawing(s) *sheets*
- ☐ Declaration with Power of Attorney
- ☐ Priority Document
- ☐ Disclosure Statement
- ☐ Form PTO-FB-A820 (Citation List) References
- ☐ Sequence Submission (☐ Computer Readable Copy, ☐ Paper copy ☐ Identity Statement)
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- ☐ Certificate of Correction
- ☒ Petition for Extension of Time 3 months
- ☐ Fee Transmittal (2 copies)
- ☐ Associate Power of Attorney
- ☐ Petition for Expedited Issuance for Foreign Filing License
- ☐ Assignment & Recordation Cover Sheet
- ☒ Response to Office Action Under 37 C.F.R §1.111
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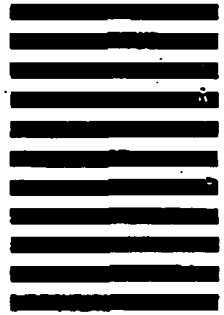

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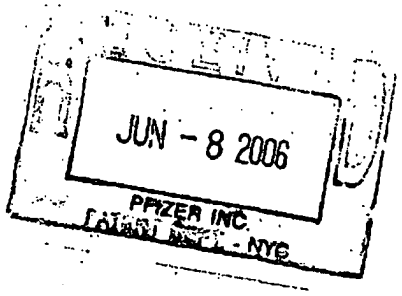
JUN - 8 2006
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EXHIBIT B